

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

### REMARKS

Reconsideration and continued examination of the present application are respectfully requested. The amendment to the claims are editorial in nature and/or further define what applicants regard as their invention. Full support for the amendment can be found throughout the present application, including the claims as originally filed. Since the claims now recite that the formulation is free of organic solvents which is a limitation previously considered by the Examiner in dependent claims as well as in some of the independent claims with respect to the phrase "substantially free of organic solvents," no new questions of patentability are raised and the amendment does not necessitate any further searching. Furthermore, the amendment places the application in immediate condition for allowance or at the very least in a better condition for appeal. Accordingly, no new matter is being introduced and for the above reasons, this amendment should be entered. Claims 1-12, 14-19, 23, and 24 are pending.

The Applicants appreciate the Examiner's indication, at page 3 of the Office Action, that the rejection of claims 1, 14, and 16 under 35 U.S.C. § 102(b) over Butler et al. has been removed.

In general, many claims use "consisting essentially of" or "consisting of" language which would be an additional reason for allowance. Clearly the formulations of the cited art used other ingredients which materially affect the properties of the formulation.

### Response to the rejection of Claims 1, 9, and 17-19 under 35 U.S.C. § 112, Second Paragraph

Claims 1, 9, and 17-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Examiner states that, with respect to claims 2 and 17-19, a definition

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

or quantification of the term "substantially free of organic solvents" is not disclosed and therefore the metes and bounds of the claimed invention are undeterminable. The Examiner states that claims 17 and 19 do not further limit claim 14. For the following reasons, the rejection is respectfully traversed.

According to MPEP §2173.05(b)(D), the term "substantially" when used in conjunction with another term to describe a particular characteristic of the claimed invention (e.g., substantially free of organic solvents) is considered definite. The applicants have amended claims 1, 14, and 17-19 to recite that the formulations are "free from organic solvents." Accordingly, the formulation of the claimed invention is substantially free of organic solvents. Additionally, the meaning of the term "organic solvent," is clear to one having ordinary skill in the art, especially in light of the portions of the specification quoted. An organic solvent does not include vegetable oil. To one of ordinary skill in the art, an organic solvent could be ethanol, xylene, and other organic solvents. Thus, the term "organic solvent" is a term widely recognized by those skilled in the art. For instance, Hawley's Condensed Chemical Dictionary (14th Ed.) (2001) clearly recognizes the term "organic solvent" and shows groups that include esters, ethers, ketones, amines, nitrated and chlorinated hydrocarbons, and the like. Clearly, this is quite different from a vegetable oil. In fact, the same Hawley's Condensed Chemical Dictionary defines vegetable oil in a manner that clearly would not be an organic solvent. Thus, the Examiner's position with respect to the term "organic solvents" is not supported by the record, and clear evidence has been submitted by the appellants to show that the Examiner's position is not accurate. Furthermore, support for recitation of free of organic solvents in the claims exists on, for example, page 4, lines 19-26, and page 7, lines 31-33 of

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

the present application. Accordingly, reconsideration is respectfully requested and the rejection under 35 U.S.C. §112, second paragraph, should be withdrawn.

**Response to the rejection of Claims 1 and 14 under 35 U.S.C. § 102(b)**

Claims 1 and 14 are rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,124,349 to Carter et al. The Examiner states that the rejection of record is maintained. The Examiner states that no water is specified in Carter et al. The Examiner further points out that Carter et al., at col. 3, lines 53-63, states that less than one percent by weight of water is present. The Examiner also states that a low percentage by weight of water is shown in Carter et al., in tables II, IV, and V. Also, the Examiner argues that neem oil is a vegetable oil. For the following reasons, the rejection is respectfully traversed.

Carter et al. does not teach the invention set forth in claims 1 and 14. Contrary to the Examiner, neem oil is not a vegetable oil. Neem oil is from the neem tree. As the Examiner should appreciate, a tree is not a vegetable. See col. 1, lines 23-27 of Larson (U.S. Patent No. 4,556,562) of record. Also see page 90, 1<sup>st</sup> col. of Dureja et al., Pesticide Research Journal, Vol. 11(1):90-92, 1999, of record. Carter et al. simply does not teach a pesticide formulation containing at least one vegetable oil. Also, Carter et al. does not teach a formulation that contains less than 2 percent by weight water, based on the weight of the formulation, and wherein said formulation is free of organic solvents, as found in claims 1 and 14. Furthermore, Carter et al. does not teach a storage stable pesticide formulation formed by mixing at least one vegetable oil, at least one non-ionic surfactant, and at least one neem extract together to form said formulation, wherein said neem extract consists of azadirachtin, and wherein said formulation contains less than 2 percent by weight

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

water, based on the weight of the formulation, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container, wherein said formulation is free of organic solvents. Accordingly, reconsideration is respectfully requested and the rejection under 35 U.S.C. §102(b) over Carter et al. should be withdrawn.

**Response to the rejection of Claims 1 and 14-16 under 35 U.S.C. § 103(a)**

Claims 1 and 14-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the article to Dimetry et al. and Carter et al. The Examiner states that the rejection of record is maintained and that, although Applicants argue that Dimetry et al. discloses water, both references use Neem oil with Azadirachtinas pesticidal composition and that Carter et al. shows the removal of water to increase stability. The Examiner states that Applicants' arguments filed on May 30, 2003, have been fully considered but are not persuasive. For the following reasons, the rejection is respectfully traversed.

As recited in claim 1, the claimed invention relates to a pesticide formulation consisting of at least one vegetable oil, at least one surfactant, and azadirachtin, wherein the formulation contains less than 2 percent by weight water, based on the weight of the formulation, wherein the formulation is free of organic solvents. The formulation of Dimetry et al. and the claimed invention differ in that Dimetry et al. only shows a formulation with large amounts of water, as can be seen from column 1 at page 396. However, the claimed invention contains less than 2 percent by weight water, based on the weight of the formulation. The lack of water is an important feature of the

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

claimed invention, because the presence of water degrades azadirachtin, as is set forth at page 5, lines 19-23 of the present application and as set forth in the Declaration of Dr. M. C. Gopinathan dated April 30, 2002.

Additionally, Dimetry et al. does not teach or suggest the use of a formulation having storage stable azadirachtin, which is recited in the claims. The formulation of Dimetry et al. is not storage stable because its formulation contains water, and azadirachtin is unstable in the presence of water and other solvents. As previously provided to the Examiner, and is of record, to further illustrate, one of the applicants conducted comparative experiments to compare the claimed invention with Dimetry et al. As shown in the Declaration of Dr. M.C. Gopinathan submitted under 37 C.F.R. §1.132 on April 30, 2002, the formulation of Dimetry et al., which contained water along with small amounts of sesame oil and a surfactant, had a very low storage stability. In other words, the storage stability of the formulation of Dimetry et al. was poor compared to the product of the claimed invention that contained substantially no water. Thus, the formulation of Dimetry et al. is not a storage stable product and is different, for the reasons stated above, from the claimed invention.

Furthermore, Dimetry et al. does not teach or suggest a storage stable formulation that contains less than 2 percent by weight water, based on the weight of the formulation, and comprises one non-ionic surfactant, as found in claim 14 of the present application, wherein the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one year of storage at 25° C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

sealed container, and wherein said formulation is free of organic solvents.

In addition to not teaching or suggesting a storage stable formulation that contains less than 2 percent by weight water, based on the weight of the formulation, wherein the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one year of storage at 25° C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container, Dimetry et al. does not teach or suggest including at least one non-ionic surfactant and sesame seed oil, as recited in claim 15 of the present application. Dimetry et al. also does not teach or suggest including sorbitan polyoxyethylene, as recited in claim 16.

The Examiner acknowledges that Dimetry et al. does not teach or suggest the claimed invention. Therefore, Examiner further argues that the deficiencies of Dimetry are resolved by Carter et al. which shows a low amount of water and further shows storage stability. However, only through the improper use of hindsight would one combine Carter et al. with Dimetry et al. Dimetry et al. shows a usable formulation in and of itself and Carter et al. does the same. As stated above, evidence has been provided previously to show the differences between Dimetry et al. and the claimed invention. Contrary to the Examiner's argument that Carter et al. teaches one to remove water to increase stability, Carter et al. actually states at column 3, lines 35-54 that neem seed extracts typically contain about 20% by volume water and if the solvent system is comprised of greater than 50% by volume aprotic solvents, then the concentration of water must be less than 15% by volume. Alternatively, if the solvent system comprises greater than 50% alcohol solvents, the concentration of water must be less than 5%. Thus, even if it was possible to combine the teachings

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

of Dimetry et al. with Carter et al., one would still not be motivated to remove the water of Dimetry et al. since Dimetry et al. does not teach or suggest the conditions for removing water which is a high amount of solvents including alcohols. In addition, Carter et al. teaches the specific use of a whole host of organic solvents in the various embodiments. Further, as stated above, Carter et al. does not teach or suggest the use of a vegetable oil. Thus, one must ask the question where is the motivation to combine Carter et al. with Dimetry et al. However, it appears the only answer is by an obvious to try standard or an improper hindsight determination. Clearly, the formulations of Carter et al. and Dimetry et al. are significantly different from each other and the Examiner cannot simply randomly choose various ingredients to combine in order to derive the claimed invention. If one combined Dimetry et al. with Carter et al., then one would also have to have a large amount of aprotic solvents or alcohols which would be contrary to the formulation of Dimetry et al. Accordingly, one skilled in the art would have no motivation to alter these formulations. Therefore, no motivation exists to alter the formulation of Carter et al. with Dimetry et al. Accordingly, the rejection of claims 1 and 14-16 under 35 U.S.C. §103(a) over Dimetry et al. and Carter et al. should be withdrawn.

**Response to the rejection of Claims 1-3, 6-9, 14, 17, and 19 under 35 U.S.C. § 102(b)**

Claims 1-3, 6-9, 14, 17, and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,885,600 to Blum et al. The Examiner states that Blum et al. shows cold extraction of Neem oil to provide solvent free Azadirachtins, along with vegetable oil, citronellas, and cedar wood, at col. 3, line 9 through col. 4, line 4. The Examiner states that Blum et al. shows that temperature, humidity, and pH can affect stability and are maintained with nitrogen, at col. 4,

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

lines 5-15. The Examiner states that non-ionic surfactants are added to permit later dilution as emulsions, at col. 4, lines 42-55, of Blum et al. The Examiner states that a solvent used is vegetable oil, at col. 4, lines 35-38, of Blum et al. The Examiner further notes that examples in Blum et al. show no water and no organic solvent, in Formulae B and C, and claims 8, 11, and 12, of Blum et al. The Examiner notes that how the formulations act is not seen as having any patentable weight. For the following reasons, the rejection is respectfully traversed.

Blum et al. does not teach the invention of claims 1-3, 6-9, 14, 17, and 19 because the claims require that the formulations be free of organic solvents. Blum et al. teaches the use of organic solvents, including Methyl Paraben USP in Formula A, Geahlene 750 in Formula B, and light mineral oil in Formula C. These compounds are well known to those of ordinary skill in the art to be organic solvents, and reference to, for example, Geahlene 750 can be found at [www.chembuyersguide.com/partners/eastech.html](http://www.chembuyersguide.com/partners/eastech.html). Accordingly, reconsideration is respectfully requested and the rejection under 35 U.S.C. §102(b) over Blum et al. should be withdrawn.

**Response to the rejection of Claims 1-4, 6-12, 14-19, 23, and 24 under 35 U.S.C. § 103(a)**

At page 4 of the Office Action, claims 1-4, 6-12, 14-19, 23, and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Blum et al. and Dimetry et al. in view of U.S. Patent No. 5,352,697 to Butler et al. The Examiner states that Blum et al. teaches the instant compositions and similar formulations, showing sufficient amounts and concentrations of active components of insect control compositions of natural ingredients, focusing on Neem tree leaf, bark, and seed extracts. The Examiner states that Blum et al. utilizes seed extracts free of added water and free of organic solvents and that Blum et al. uses vegetable oil solvents. The Examiner states that Blum et



Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

al. shows added surfactants, including non-ionic PEG in formula C, Azadirachtins extracted by cold press extraction, and Neem oil concentrations as high as 50%, at the bottom of column 3. The Examiner states that sealed containers are disclosed at col. 4, lines 5-15 and that the compositions of Blum et al. are storage stable. The Examiner notes that sesame oil was not mentioned.

The Examiner states that Butler et al. teaches the particular surfactant, inclusive of triglycerides and ethoxylated sorbitan, at col. 5, lines 14-30, when preparing Azadirachtin derivatives, as seen in Example 10. The Examiner also states that Butler et al. shows Neem seed extracts with concentrations of up to 50%, as shown in claim 21. The Examiner states that Dimetry et al. shows that sesame oil enhances the insecticidal activity of Neem seed extracts, at the last paragraph of p. 396.

At pages 4 and 5 of the Office Action, the Examiner states that one of ordinary skill in the art would find it obvious to prepare particular ingredient combinations, concentrations, and ratios depending upon the target species, desired number of applications, length of time for desired protection, ease of handling, and degradation. The Examiner states that the claimed invention provides well known prior art compounds having well known effects, applied by well known prior art methods to achieve well known control over pests.

The Examiner states that the primary reference discloses the essence of the claimed invention but does not specify each and every element. The Examiner states that the secondary references do provide the additional elements.

The Examiner states that Applicants have not clearly established by objective showing of critical, unobvious and/or unexpected results that the particular form of active ingredient, carrier, or

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

extract provides any new or unexpected results. For the following reasons, the rejection is respectfully traversed.

Blum et al. does not teach the invention of claims 1-3, 6-9, 14, 17, and 19 because the claims require that the formulations be free of organic solvents. As stated above, Blum et al. teaches the use of organic solvents, including Methyl Paraben USP in Formula A, Geahlene 750 in Formula B, and light mineral oil in Formula C. These compounds are well known to those of ordinary skill in the art to be organic solvents, and reference to, for example, Geahlene 750 can be found at [www.chembuyersguide.com/partners/eastech.html](http://www.chembuyersguide.com/partners/eastech.html).

The Butler et al. formulation and the claimed invention differ, at least, in that Butler et al. does not teach a formulation that contains less than 2 percent by weight water, based on the weight of the formulation. The lack of water is an important feature of the claimed invention, since the presence of water degrades azadirachtin, as is set forth at page 5, lines 19-23 of the present application. Additionally, neem seed usually contains 30-40% moisture during harvest and dried neem seed usually contains 10-15% water. Accordingly, although Butler et al. does not specifically mention the presence or absence of water, it seems inherent that the formulation of Butler, et al. includes water. Furthermore, most of the examples in Butler et al. use the traditional organic solvents instead of vegetable oils. For example, in example 1 of Butler et al., ethanol, ethyl acetate, acetonitrile, isopropanol, methanol, and the like are used. Likewise, examples 2-10 in Butler et al. show azadirachtin containing neem seed extract in an aromatic petroleum distillate, which is an organic solvent. The advantages of not using organic solvents are illustrated at, for example, page 7, lines 31-33 of the present application.

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

The formulation of Dimetry et al. and the claimed invention differ in that Dimetry et al. only shows a formulation with water, as can be seen from column 1 at page 396. However, the claimed invention contains less than 2 percent by weight water, based on the weight of the formulation. Additionally, Dimetry et al. does not teach or suggest the use of a formulation having storage stable azadirachtin. The formulation of Dimetry et al. is not storage stable because its formulation contains water, and azadirachtin is unstable in the presence of water and other solvents. As shown in the Declaration of Dr. M.C. Gopinathan submitted under 37 C.F.R. §1.132 on April 30, 2002, the formulation of Dimetry et al., which contained water along with small amounts of sesame oil and a surfactant, had a very low storage stability. In other words, the storage stability of the formulation of Dimetry et al. was poor compared to the product of the claimed invention that contained no water. Thus, the formulation of Dimetry et al. is not a storage stable product and is different, for the reasons stated above, from the claimed invention.

Furthermore, Dimetry et al. does not teach or suggest a storage stable formation that contains less than 2 percent by weight water, based on the weight of the formulation, and comprises at least one non-ionic surfactant, wherein the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one year of storage at 25° C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container, and wherein said formulation is free of organic solvents.

In addition, Dimetry et al. does not teach or suggest including at least one non-ionic surfactant and sesame seed oil or including sorbitan polyoxyethylene

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

Dimetry et al. and Blum et al. do not teach or suggest the claimed invention. However, only through the improper use of hindsight would one combine Blum et al. and/or Dimetry et al. with Butler et al. All three references show a usable formulation in and of themselves. As stated above, evidence has been provided previously to show the differences between Blum et al. and Dimetry et al. and the claimed invention. Accordingly, one skilled in the art would have no motivation to alter these formulations. Therefore, no motivation exists to alter the formulation of Blum et al. and Dimetry et al. with Butler et al. Accordingly, reconsideration is respectfully requested and the rejection under 35 U.S.C. §103(a) over Blum et al. and Dimetry et al. in view of Butler et al. should be withdrawn.

Application No. 09/536,351  
Amendment dated December 2, 2003  
Reply to Office Action of September 2, 2003

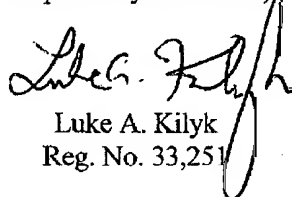
### **CONCLUSION**

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

Should the Examiner deem that any further action by Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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